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105TH CONGRESS
2D SESSION

H. R. 3815

To amend the Internal Revenue Code of 1986 to provide for a medical innovation tax credit for clinical testing research expenses attributable to academic medical centers and other qualified hospital research organizations.

IN THE HOUSE OF REPRESENTATIVES

MAY 7, 1998

Mr. SAM JOHNSON of Texas (for himself, Mr. LEVIN, Mr. ENGLISH of Pennsylvania, Mr. HOUGHTON, Mr. PRICE of North Carolina, Ms. LOFGREN, Mr. DOOLEY of California, and Mr. BENTSEN) introduced the following bill; which was referred to the Committee on Ways and Means

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A BILL

To amend the Internal Revenue Code of 1986 to provide for a medical innovation tax credit for clinical testing research expenses attributable to academic medical centers and other qualified hospital research organizations.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. CREDIT FOR CLINICAL TESTING RESEARCH EXPENSES ATTRIBUTABLE TO CERTAIN QUALIFIED ACADEMIC INSTITUTIONS INCLUDING TEACHING HOSPITALS.

(a) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to business related credits) is amended by inserting after section 41 the following:

"SEC. 41A. CREDIT FOR MEDICAL INNOVATION EXPENSES.

"(a) GENERAL RULE.—For purposes of section 38, the medical innovation credit determined under this section for the taxable year shall be an amount equal to 20 percent of the excess (if any) of—

"(1) the qualified medical innovation expenses for the taxable year, over

"(2) the medical innovation base period amount.

"(b) QUALIFIED MEDICAL INNOVATION EXPENSES.—For purposes of this section—

"(1) IN GENERAL.—The term 'qualified medical innovation expenses' means the amounts which are paid or incurred by the taxpayer during the taxable year directly or indirectly to any qualified academic institution for clinical testing research activities.

"(2) CLINICAL TESTING RESEARCH ACTIVITIES.—

''(A) IN GENERAL.—The term 'clinical testing research activities' means human clinical testing conducted at any qualified academic institution in the development of any product, which occurs before—

''(i) the date on which an application with respect to such product is approved under section 505(b), 506, or 507 of the Federal Food, Drug, and Cosmetic Act,

''(ii) the date on which a license for such product is issued under section 351 of the Public Health Service Act, or

''(iii) the date classification or approval of such product which is a device intended for human use is given under section 513, 514, or 515 of the Federal Food, Drug, and Cosmetic Act.

''(B) PRODUCT.—The term 'product' means any drug, biologic, or medical device.

''(3) QUALIFIED ACADEMIC INSTITUTION.—The term 'qualified academic institution' means any of the following institutions:

''(A) EDUCATIONAL INSTITUTION.—A qualified organization described in section 170(b)(1)(A)(iii) which is owned or affiliated

with an institution of higher education as described in section 3304(f).

''(B) CHARITABLE RESEARCH HOSPITAL.—A charitable research hospital which—

''(i) is owned by an organization described in section 501(c)(3) and exempt from taxation under section 501(a),

''(ii) is not a private foundation, and

''(iii) is designated as a cancer center by the National Cancer Institute.

''(4) EXCLUSION FOR AMOUNTS FUNDED BY GRANTS, ETC.—The term 'qualified medical innovation expenses' shall not include any amount to the extent such amount is funded by any grant, contract, or otherwise by another person (or any governmental entity).

''(c) MEDICAL INNOVATION BASE PERIOD AMOUNT.—For purposes of this section, the term 'medical innovation base period amount' means the average annual qualified medical innovation expenses paid by the taxpayer during the 3-taxable year period ending with the taxable year immediately preceding the first taxable year of the taxpayer beginning after December 31, 1997.

''(d) SPECIAL RULES.—

''(1) LIMITATION ON FOREIGN TESTING.—No credit shall be allowed under this section with respect to any clinical testing research activities conducted outside the United States.

''(2) CERTAIN RULES MADE APPLICABLE.—Rules similar to the rules of subsections (f) and (g) of section 41 shall apply for purposes of this section.

''(3) ELECTION.—This section shall apply to any taxpayer for any taxable year only if such taxpayer elects (at such time and in such manner as the Secretary may by regulation prescribe) to have this section apply for such taxable year.

''(4) COORDINATION WITH CREDIT FOR INCREASING RESEARCH EXPENDITURES AND WITH CREDIT FOR CLINICAL TESTING EXPENSES FOR CERTAIN DRUGS FOR RARE DISEASES.—Any qualified medical innovation expense for a taxable year to which an election under this section applies shall not be taken into account for purposes of determining the credit allowable under section 41 or 45C for such taxable year.''

(b) GENERAL BUSINESS CREDIT.—Section 38(b) of the Internal Revenue Code of 1986 (relating to current year business credit) is amended by striking ''plus'' at the end of paragraph (11), by striking the period at the end

of paragraph (12) and inserting ", plus", and by adding at the end the following:

"(13) the medical innovation expenses credit determined under section 41A(a)."

(c) DEDUCTION FOR UNUSED PORTION OF CREDIT.—Section 196(c) of the Internal Revenue Code of 1986 (defining qualified business credits) is amended by striking "and" at the end of paragraph (6), by striking the period at the end of paragraph (7) and inserting ", and", and by adding at the end the following:

"(8) the medical innovation expenses credit determined under section 41A(a)."

(d) CONFORMING AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by adding after the item relating to section 41 the following:

"Sec. 41A. Credit for medical innovation expenses."

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1997.

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